

**REMARKS**

This Amendment is filed in response to the non-final Office Action dated March 5, 2008, and is respectfully submitted to be fully responsive to the rejections raised therein. Accordingly, favorable reconsideration on the merits and allowance are respectfully requested.

In the present Amendment, claims 1 and 35 have been amended to incorporate the subject matter of claims 2 and 6.

Claims 2-6, 14-19, 22-24, 30, 31 and 45 have been canceled.

Claims 7, 20, 21, 25-27, and 32 have been amended to depend from claim 1.

Claim 33 has been amended to further define ring B<sup>1</sup>.

Claims 36, 38, and 47-49 have been amended to improve their form.

Claims 38, 44 and 46 have been amended to delete the terms “preventing” and/or “preventive” from the claims.

No new matter has been added. Entry of the Amendment is respectfully submitted to be proper. Upon entry of the Amendment, claims 1, 7-13, 20, 21, 25-29, 32-44 and 46-49 will be all the claims pending in the application.

**I. Response to Claim Objections**

Claims 35-43 and 47-49 are provisionally objected to under 37 C.F.R. § 1.75 as being substantial duplicates of claim 1. Claim 26 is objected to because the claim assertedly ends with a comma and not a period.

Applicants traverse and request withdrawal of the objection in view of the Amendments to the Claims and in further view of the following remarks.

Claim 35, directed to a pharmaceutical composition, has been amended to further recite a pharmaceutical acceptable carrier. Applicants respectfully submit that claim 1 and claims 35-43 and 47-49 are not substantial duplicates as claim 1 is drawn to a compound and claim 35 is drawn to a composition. Thus, the claims are different.

Furthermore, claim 26 has been amended by inserting a period at the end of the claim. Accordingly, Applicants respectfully request that the objection be withdrawn.

## **II. Response to Rejection Under 35 U.S.C. § 112 – Written Description**

Claims 1, 2, 4-32, 35-43 and 46-49 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement.

Applicants traverse and request withdrawal of the rejection in view of the Amendments to the Claims and in further view of the following remarks.

The pertinent test for determining if a specification meets the written description requirement is whether Applicants' disclosure clearly allows a person of ordinary skill in the art to recognize that as of the filing date he or she invented what is claimed.<sup>2</sup> It is established that a description filed is presumed to be adequate unless there is sufficient evidence to the contrary presented by the examiner. Regarding claims drawn to a genus, section 2163 (ii) of the M.P.E.P.

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<sup>2</sup> M.P.E.P. § 2163.02.

states in relevant part that “[t]he written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by combination of such identifying characteristics, sufficient to show that the applicant was in possession of the claimed genus.”<sup>3</sup> For claims drawn to a species, the written description requirement for the genus may be satisfied through a sufficient description of a representative number of species.

In this case, the specification describes various species of formula (I) drawn to pyrazine and quinoxaline and discloses identifying characteristics (e.g., TLC, NMR) of these compounds. Furthermore, the specification states that “the compound of formula (I) may be prepared by combining known methods, such as the methods in the Examples or the methods described in Larock, *Comprehensive Organic Transformations: A Guide to Functional Group Preparations*.<sup>4</sup> The specification clearly describes formula (I) and each variable recited in formula (I). The specification also teaches examples of each of ring variables A, B, and D (i.e., C<sub>3-15</sub> monocyclic includes cyclohexene) and each spacer variable (i.e., G has 1 to 4 atoms in its main chain). The specification discloses representative number of examples of claimed compound that are encompassed within the genus of Formula (I), for example, 2-((pyridine-3-yl)methyloxy)-3-(4-chlorophenylsulfonylamino)quinoxaline (Example 5(3)) and 2-((3-(2-dimethylaminoethoxy)-4-methoxyphenyl)methyloxy)-3-(4-methylphenylsulfonylamino) pyrazine (Example 3(6)). Thus, it

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<sup>3</sup> M.P.E.P. § 2163 (ii).

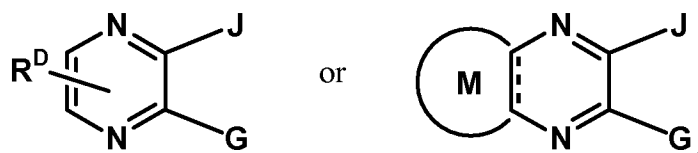
<sup>4</sup> Specification, pg. 69, lines 28-32.

is clear that the specification meets the written description requirement for the compound of formula (I), especially where the D ring is a mono- or poly- cyclic ring containing pyrazine.

Applicants further submit that the examples disclosed in the specification and the method of making the subgenus compounds represent a representative number of species encompassed in the genus because a person of ordinary skill in the art could predict the operability of the invention based on the disclosure. The specification need not be in *ipsis verbis* to be sufficient. For Example, the compound of formula (I-A) in the present application, wherein J is bound to ring D via an oxygen atom, can be prepared by method (a-1) or (b-1); that the compound of formula (I-B), wherein G is bound to ring D via  $\text{-NHSO}_2\text{-}$ , is prepared by a method (a-2) or (b-2); and that the compound of (I-C), wherein G is bound to ring D via  $\text{-NHCO-}$ , is prepared by subjecting the compound of formula (VI) and a compound of formula (X) to amidation, and if necessary, to a deprotection reaction and/or to cleavage reaction from a resin.

Furthermore, the present specification states that other compounds of formulae (II) to (XXV) used as starting materials or reagents are known *per se* or may be prepared by known methods, such as those methods described in Larock, *Comprehensive Organic Transformations: A Guide to Functional Group Preparations*, 2<sup>nd</sup> Edition, John Wiley & Sons, Inc. 1999. Based on the aforementioned, an ordinary artisan could predict the operability in the invention of any species encompassed in the genus, in addition to the enumerated species in the Examples, and therefore would have understood the inventor to be in possession of the claimed invention at the time of filing.

However, without acquiescing to the merits of the rejection, claims 1 and 35 have been amended to limit the D ring in formula (I) to represent:



Claims 1 and 35 have also been amended so that ring B represents a monocyclic carbocyclic ring structure. Furthermore, variable J has been amended to represent  $-\text{OC}(\text{R}^3\text{R}^4)\text{E}-$  and variable G has been amended to represent  $-\text{NR}^{\text{T1}}-\text{SO}_2-$ .

In view of the Amendments to the Claims, Applicants submit that the specification meets the written description requirement. Accordingly, Applicants request that the rejection be withdrawn.

### **III. Response to Rejection Under 35 U.S.C. § 112 – Lack of Enablement**

Claims 1, 2, 4-33, 35-43, and 46-49 are rejected under 35 U.S.C. § 112, first paragraph, because according to the Examiner, the specification, while being enabling for 2,3-disubstituted pyrazine rings, where the 2-position is attached to an oxygen and optionally a linker of atoms with a ring, and the 3-position is attached to an aminosulfonyl group attached directly to a thienyl or phenyl group does not reasonably provide enablement for all other compounds not previously mentioned.

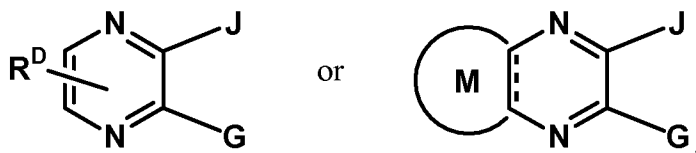
Applicants traverse and request withdrawal of the rejection in view of the Amendments to the Claims and in further view of the following remarks.

MPEP §2164.01 (a) states, “A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the

claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).”

Applicants submit that the specification meticulously sets forth various processes of manufacturing every possible subgenus of formula (I). For example, the specification teaches that the compound of formula (I-A), wherein J is bound to ring D via an oxygen atom, is prepared by method (a-1) or (b-1); that the compound of formula (I-B), wherein G is bound to ring D via  $\text{-NHSO}_2\text{-}$ , is prepared by a method (a-2) or (b-2); and that the compound of (I-C), wherein G is bound to ring D via  $\text{-NHCO-}$ , is prepared by subjecting the compound of formula (VI) and a compound of formula (X) to amidation, and if necessary, to deprotection reaction and/or to cleavage reaction from a resin.

Furthermore, without conceding to the merits of the rejection, claims 1 and 35 have been amended to limit the D ring in formula (I) to represent:



Claims 1 and 35 have also been amended so that ring B represents a monocyclic carbocyclic ring structure. Furthermore, variable J has been amended to represent  $\text{-OC(R}^3\text{R}^4\text{)E-}$  and variable G has been amended to represent  $\text{-NR}^{\text{T1}}\text{-SO}_2\text{-}$ .

In view of the Amendments to the Claims, Applicants submit that the specification meets the written description requirement. Accordingly, Applicants request that the rejection be withdrawn.

**IV. Response to Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 36-43 and 46-49 are rejected under 35 U.S.C. § 112 as allegedly being indefinite for failing to particularlry point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants traverse and request that the rejection be withdrawn in view of the amendments to claims 36, 38 and 46-49. Claims 37 depends from claim 36 and claims 39-43 depend from claim 38 either directly or indirectly and are therefore definite for the reasons indicated for claim 36 and 38. Withdrawal of the rejection is respectfully requested.

**V. Response to Rejection Under 35 U.S.C. § 102(b)**

Claims 1, 2, 4-8, 10, 12, 14, 16, 18, 20, 22-26, 30-33, 35-43 and 46-49 are rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Bradbury, *et al.*, Journal of Medicinal Chemistry (1997), 40(6), 996-1004 (“Bradbury”).

Applicants traverse and request withdrawal of the rejection in view of the Amendments to the Claims and in further view of the following remarks.

Applicants respectfully submit that claims 1 and 35, as amended, do not read on the subject matter described in Bradbury. Specifically, ring B represents a monocyclic carbocyclic ring and cannot represent a polycyclic aromatic ring (e.g. naphthalene ring).

Furthermore, Applicants submit that claim 7 does not read on the compounds described in Bradbury. Claim 7 recites fused heterocyclic ring systems. The compound 7l of Bradbury has

a pyrazinyl core and clearly is not within the scope of claim 7. Accordingly, claim 7 does not read on Bradbury. Withdrawal of the rejection of claim 7 is therefore requested.

The rejection over claims 2, 4-6, 14, 16, 18, 22-24, 30, and 32 is moot as these claims have been canceled.

Claims 7, 8, 10, 12, 20, 25, 26, 32, 33 and 46 depend from claim 1 either directly or indirectly and are therefore patentable over Bradbury for at least the reasons mentioned with respect to claim 1. Similarly, claims 36-43 and 47-49 depend from claim 35 either directly or indirectly and are therefore patentable over Bradbury for at least the reasons mentioned with respect to claim 35. Accordingly, withdrawal of the rejection is respectfully requested.

#### **VI. Provisional Obviousness-type Double Patenting Rejection**

Claims 1, 2, 4-33, 35-43, and 46-49 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-28 and 30 of U.S. Patent Publication Application No. 2007/0254886.

Applicants respectfully request that the rejection be held in abeyance until allowable subject matter has been indicated in one of the applications.

#### **VII. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the



Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

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Sunhee Lee  
Registration No. 53,892

WASHINGTON DC SUGHRUE/265550

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CUSTOMER NUMBER

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